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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/080,130 | 02/19/2002 | Romano Deghenghi | 87264-300 | 9172 |
| 28765 | 7590 | 09/01/2004 | EXAMINER | |
| WINSTON & STRAWN PATENT DEPARTMENT 1400 L STREET, N.W. WASHINGTON, DC 20005-3502 | | | SPEAR, JAMES M | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,130

Applicant(s)

DEGHENGHI ET AL.

Examiner

James M Spear

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 and 32-57 is/are pending in the application.
- 4a) Of the above claim(s) 32-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9-15 and 20-29 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 16-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

The amendment submitted May 04, 2004 has been entered.

1. Newly submitted claims 32-57 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The original independent claims 1, 12 and 29 are directed to a method of preparing a sustained release formulation of a peptide or peptidomimetic, a fluid milky microcrystalline aqueous suspension of a peptide or peptidomimetic and a counter-ion of a strong proton donor in water and a method of preparing a fluid milky microcrystalline aqueous suspension of a peptide or peptidomimetic, which are broad generic claims while new claims 32-57 are directed to species of invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 32-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-4, 9-15 and 20-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The factors to be considered in determining whether a disclosure meets

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the enablement requirement of 35 U.S.C. 112 first paragraph have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1. The nature of the invention; 2. The state of the prior art; 3. The relative skill of those in the art; 4. The predictability or unpredictability of the art; 5. The breath of the claims; 6. The amount of direction or guidance presented; 7. The presence or absence of working examples and 8. The quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1. The nature of the invention: The presently claimed invention is directed to a method of preparing a sustained release formulation of a peptide or peptidomimetic and a fluid milky suspension of said formulation. The peptide is suspended at a particular concentration of at least 25 mg/ml.

2. The state of the prior art: The prior art shows pharmaceutical formulations comprised of reaction products of peptides considered pertinent to applicants' however applicants' concentration is not disclosed.

3. The relative skill of this in the art is considered high.

4. The unpredictability of the peptide art is considered very high. The significance of particular amino acids or sequences for different aspects of biological activity cannot be predicted a priori but must be determined on a case by case basis requiring experimental study. Since the claims broadly encompass any peptide it is not clearly evident how one can predict any peptide forming such a distinct sustained release formulation having the required efficacy. There is a general lack of predictability in the pharmaceutical art. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) Therefore how one can effectively predict a method of preparing sustained release formulations of any peptide

having such distinct properties that will be equally effective no matter what peptide is utilized is not clearly evident. 5. The breadth of the claims. The claims are very broad and all encompassing for a formulation having very distinct properties. While the specification list more than one peptide, the limited number disclosed is not considered adequate to support claims directed to any peptide or peptidomimetic. Neither does the specification provide evidence to determine what is within the scope of analogues as disclosed. 6. The amount of direction or guidance presented. While the specification states any peptide can be utilized there is no description given defining the properties, characteristics, or other scientific data presented that one may use to distinguish between the degree of efficacy such peptides will have in the claimed invention. Certain peptides are described as being preferred but no indication as to what makes them preferred. The limited number disclosed is not considered representative of any peptide as claimed. 7. While examples are presented, the 13 examples are limited to 3 peptides or analogues. This is not consistent with a disclosure that supports such a broad claimed genus. 8. Since different aspects of biological activity cannot be predicted but must be determined from case to case by painstaking experimental study from such methods involving sustained release formulations one of ordinary skill in the art would be burdened with undue experimentation. Claims broadly reciting peptides or peptidomimetics are not commensurate in scope with an enabling disclosure. When the above factors are weighed it is the position of the examiner that one skilled in the art could not practice the invention without undue experimentation.

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4. Claims 5-8 and 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 32-57 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 30 and 31 have been canceled.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M Spear whose telephone number is 571 272 0605. The examiner can normally be reached on Monday thru Friday from 6:30 AM to 3 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page, can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James M. Spear

JAMES M. SPEAR
PRIMARY EXAMINER

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08-30-04